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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,425	07/27/1999	JOHN KUNG	JBP461	5503

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/361,425

Applicant(s)

KUNG ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 15, 17, 18 and 21-24 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of the Claims

1. Claims 7, 14-24 are pending.

Applicants' amendment filed on February 4, 2002 (Paper No. 21) is acknowledged, and applicants' response has been fully considered. Claims 1-6 and 8-13 have been cancelled, claims 7 and 15 have been amended, new claims 17-24 have been added. Claims 14 and 16 stand withdrawn from consideration. Thus, claims 7, 15 and 17-24 are examined.

Objection Withdrawn

2. The previous rejection of claim 1 regarding the term "one or more stabilizer compounds selected from the group consisting of: a) thio-containing compounds" is withdrawn in view of cancellation of claim 1, and applicants' response at page 3 in Paper No. 21.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 2, 5-7, 8-13 and 15 under 35 U.S.C.112, second paragraph, regarding the terms "one or more stabilizer compounds" and "more than one oxygen-labile species", as well as no antecedent basis in claim 6, is withdrawn in view of applicants' cancellation of claims 1-6 and 8-13, applicants' amendment to claims 7 and 15, and applicants' response at page 4 in Paper No. 21.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1, 2, 5, 6 and 10-12 under 35 U.S.C.102(b), as being anticipated by Clum *et al.* (WO 93/00085) is withdrawn in view of applicants' cancellation of the claim and applicants' response at pages 3-4 in Paper No. 21.

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5. The previous rejection of claims 1, 2, 5, 6 and 8-13 under 35 U.S.C.102(b), as being anticipated by Liu *et al.* (WO 97/31620) is withdrawn in view of applicants' cancellation of the claim and applicants' response at page 4 in Paper No. 21.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7, 15, 17, 18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 15, 17, 18 and 21 are indefinite because of the use of the term "derivatives", "from one to about three", "from about one to about three", "at least one stabilizer compound", "at least one retinoid", "at least one tocopherol" or "at least one ascorbic acid". The term "derivatives", "from one to about three", "from about one to about three", "at least one stabilizer compound", "at least one retinoid", "at least one tocopherol" or "at least one ascorbic acid" renders the claim indefinite, it is unclear what structure the derivative has and how different the derivative is as compared to the parent compound, and how many oxygen-labile species are in the composition, e.g., are oxygen-labile species in the range of one to three, or more than three? It is also unclear how many stabilizer compounds, retinoids, tocopherols or ascorbic acids are in the composition. Claims 17, 18 and 21 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the term "derivative" is well known to those of skill in the art, they are the compounds that are related to and derived from the described compounds,

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and further provide two references (International Cosmetic Ingredient Dictionary and Handbook (7th Edition); Cosmetic Handbook (1997)) to indicate examples of tocopherol and ascorbic acid derivatives. The argument is not found persuasive because a derivative can be a compound having any modification of the parent compound, and the structure of the derivative is not defined without specifying the modification. Therefore, it is not clear what structure the derivative has.

7. Claims 7 and 18 are indefinite because of the use of the term “a mixture thereof”. The term “a mixture thereof” renders the claim indefinite, it is unclear how many oxygen-labile species and what amount of each species is contained in the composition. Note that claim 18 cites Markush group, however, an open language “a mixture thereof” is used.

8. Claim 17 is indefinite because of the use of the term “at least two oxygen-labile species”. The term “at least two oxygen-labile species” renders the claim indefinite, it is unclear how many oxygen-labile species are contained in the composition.

9. Claim 21 is indefinite because of the use of the term “an antioxidant”. The term “an antioxidant” renders the claim indefinite, it is unclear the oxygen-labile species and antioxidants are mutually exclusive.

10. Claims 22-24 are indefinite because of the use of the term “from about ...to about”. The term “from about ...to about” renders the claim indefinite, it is unclear the amount of retinoid, tocopherol, ascorbic acid or N-acetylcysteine is in the cited range or outside the range.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 7, 15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Malfroy-Camine *et al.* (U. S. Patent 5,403,834).

Malfroy-Camine *et al.* teach a pharmaceutical composition contains a salen-transition metal complex which can be administered alone or in combination with one or more free radical scavengers such as tocopherol, ascorbic acid and N-acetylcysteine, the pharmaceutical composition functions as an in vivo antioxidant and the formulation of the composition is dependent upon the pathological conditions (column 5, lines 34-38; column 6, lines 7-22; claims 7, 15 and 21).

12. Claims 7, 15 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bland (U. S. Patent 5,637,324).

Bland teaches a dietary composition comprising 0.05-0.25% by weight of calcium ascorbate, 0.1-0.4% of D- α -tocopherol, and 0.08-0.22 % of N-acetylcysteine (preferably 0.1%), (column 1, lines 59-60; column 2, lines 35-37, 41-44, 51-52; column 5, lines 3-23, 34-39; claims 7, 15 and 23).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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13. Claims 7, 15, 18 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Cruz (U. S. Patent 5,843,481).

Cruz teaches a pharmaceutical composition comprising a vanadate compound or a vanadate compound in combination with one or more antioxidants including ascorbic acid, α -tocopherol, N-acetylcysteine and a flavonoid, and effective amounts of the vanadate compound and the antioxidants are used (column 5, lines 25-47; column 6, lines 56-61; column 5; claims 7, 15, 18 and 21). Riboflavin is an example of flavonoid.

14. Claims 7 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Fisher *et al.* (WO 98/55075).

Fisher *et al.* teach a composition for ameliorating various effects of UV radiation comprising effective amounts of retinoid and antioxidants such as ascorbic acid and N-acetylcysteine (page 5, lines 1-4; page 15, line 27-page 16, line 32; claims 7 and 15).

15. Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

April 24, 2002

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